Exhibit 16

2019 WL 341909
Only the Westlaw citation is currently available.
United States District Court,
S.D. Ohio, Eastern Division.

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846
|
Signed 01/28/2019

OPINION AND ORDER

EDMUND A. SARGUS, JR., CHIEF UNITED STATES DISTRICT JUDGE, KIMBERLY A. JOLSON, UNITED STATES MAGISTRATE JUDGE

***1** This matter is before the Court on Plaintiffs' Motion to Compel Production of Certain Foreign Regulatory Documents (Doc. 78). For the reasons that follow, Plaintiffs' Motion is **GRANTED in part and DENIED in part**. Specifically, Defendants are **ORDERED** to produce official communications between Defendants and the six regulatory authorities identified in Plaintiffs' Motion (*id.* at 3–4) regarding the safety and labeling of polypropylene hernia mesh products identified in paragraph 15 of the Master Long Form Complaint. The parties are **ORDERED** to meet and confer regarding a reasonable time-period applicable to that discovery request.

I. BACKGROUND

Plaintiffs are requesting that the Court compel Defendants to produce foreign regulatory materials relating to polypropylene surgical mesh. (*See generally id.*). Plaintiffs made the initial request for these materials in their First Set of Request for the Production of Documents, which was served on September 5, 2018, (*Id.* at 3). Through the meet and confer process, Plaintiffs have narrowed their request "to communications relating to the safety and labeling of polypropylene surgical mesh products" between Defendants and a limited number of foreign regulatory authorities, specifically:

1. the Scientific Committees of the European Commission;
2. the Medicines and Healthcare Products Regulatory Agency (MHRA), including Scotland's Health Facilities Scotland (HFS) and the National Health Services (NHS) (United Kingdom);
3. the Federal Institute for Drugs and Medical Devices (BfArM) (Germany);
4. Health Canada;
5. the Therapeutic Goods Administration (TGA) (Australia); and
6. the Pharmaceuticals & Medical Devices Agency (PMDA) (Japan).

(*Id.* at 3–4). Relevant here, Plaintiffs are "asking for the official regulatory file containing the communications and submissions between Defendants' implicated subsidiary or affiliate and the regulatory authority at issue." (*Id.*).

The parties disagree as to whether the foreign regulatory materials are relevant and whether their production would be too burdensome. They have been unable to resolve this dispute extrajudicially, which led to the instant Motion. Defendants filed a Response in Opposition (Doc. 87), and Plaintiffs filed a Reply (Doc. 90). The Motion is now ripe for resolution.

II. STANDARD OF REVIEW

"Determining the proper scope of discovery falls within the broad discretion of the trial court." *Gruenbaum v. Werner Enter., Inc.*, 270 F.R.D. 298, 302 (S.D. Ohio 2010) (citing *Lewis v. ACB Business Servs., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998)). According to Rule 26(b), "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). "On notice to other parties and all affected persons, a party may move for an order compelling disclosure or discovery." Fed. R. Civ. P. 37(a)(1). The moving party bears the burden of demonstrating relevance. *Gruenbaum*, 270 F.R.D. at 302 (citation omitted). "If the movant makes this showing, 'then the burden shifts to the non-movant to show that to produce the information would be unduly burdensome.' " *Ball v. Kasich*, No. 2:16-CV-282, 2018 WL 6242230, at *3 (S.D. Ohio Nov. 29, 2018) (quoting *Prado v. Thomas*, No. 3:16-cv-306, 2017 WL 5151377, at *1 (S.D. Ohio Oct. 19, 2017)).

III. ANALYSIS

***2** The parties generally dispute whether Plaintiffs' request for foreign regulatory materials is (1) relevant, (2) proportional to the needs of the case, and (3) premature. The Court addresses each of these arguments in turn.

A. Relevance

"Federal Rule of Civil Procedure 26 allows for broad discovery in litigation, including 'any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.' " *FCA US LLC, v. Patrea Bullock*, No. 17-CV-13972, 2019 WL 258169, at *2 (E.D. Mich. Jan. 18, 2019) (alteration omitted) (quoting Fed. R. Civ. P. 26(b)(1)); *see also Commerce & Indus. Ins. Co. v. Century Sur. Co.*, No. 2:16-CV-320, 2017 WL 946984, at *3 (S.D. Ohio Mar. 10, 2017) (recognizing "the broad scope of discovery permitted by the Federal Rules").

As explained below, a narrowed version of Plaintiffs' discovery request satisfies this liberal standard. And, in its discretion, the Court will limit the scope of discovery to official communications between Defendants and the six regulatory authorities identified above regarding the safety and labeling of polypropylene hernia mesh products identified in paragraph 15 of the Master Long Form Complaint (Doc. 67).

As in most products liability cases, notice and causation are central issues here. The requested foreign regulatory materials are relevant to those issues because Plaintiffs can use them "to discover what Defendants knew about the potential risks of the products at issue here, when Defendants knew about those potential risks, what follow-up investigations Defendants did to learn more about those potential risks, and other facts that are potentially relevant...." *Hardy v. Pharmacia Corp.*, No. 4:09-CV-119 CDL, 2011 WL 2118983, at *3 (M.D. Ga. May 27, 2011); (*see also* Doc. 78-3 at 3–7 (same); Doc. 46 at 4 (finding that information regarding "whether Defendants had additional knowledge of safety information concerning" the products at issue to be relevant)). The authorities cited by Plaintiffs confirm this conclusion. (*See* Doc. 78 at 7–8 (collecting cases)).

Defendants respond that foreign regulatory materials do not matter here because this case concerns United States resident plaintiffs who used hernia mesh products approved by the United States Food and Drug Administration and that all of the events underlying this case occurred in the United States. (Doc. 87 at 7–8). Plaintiffs and the Court agree with Defendants on this factual point, but not its legal significance. Regardless of the country in which Defendants and their subsidiaries operate, Defendants are obligated to notify regulatory authorities of potential health and safety risks associated with their products. As discussed above, foreign regulatory materials may therefore be relevant to the extent they contain information about what Defendants knew about the alleged risks associated with their hernia mesh products, when they knew about those alleged risks, and whether those alleged risks were communicated to physicians and patients.

Moreover, Defendants' argument that courts have often excluded evidence regarding foreign regulatory standards at trial is misplaced. (*See id.* at 8–11 (collecting cases)). Admissibility at trial does not determine relevancy for discovery purposes. *See* Fed. R. Civ. P. 26(b)(1) ("Information within the scope of discovery need not be admissible in evidence to be discoverable.").

***3** Plaintiffs have therefore shown that official communications between Defendants and the six regulatory authorities identified above regarding the safety and labeling of polypropylene hernia mesh products identified in paragraph 15 of the Master Long Form Complaint are relevant here. The relevance of foreign regulatory materials regarding products not at issue in this case is less clear to the Court. Accordingly, to the extent Plaintiffs' Motion requests those materials, it is DENIED without prejudice. If Plaintiffs seek such materials at a later date, they must more clearly demonstrate relevancy.

B. Proportionality

Rule 26, which governs the scope of discovery and its limits, provides in relevant part:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues,

> and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). The rule "is intended to encourage judges to be more aggressive in identifying and discouraging discovery overuse by emphasizing the need to analyze proportionality before ordering production of relevant information." *BlackRock Allocation Target Shares: Series S Portfolio v. Wells Fargo Bank, Nat'l Ass'n*, No. 14CIV10067KPFSN, 2017 WL 3610511, at *6 (S.D.N.Y. Aug. 21, 2017) (citation and internal quotation marks omitted).

The Rule 26(b)(1) factors weigh in favor of an order compelling the production of the discovery, as narrowed by the Court, here. First, the issues of notice and causation are central to this action. The requested foreign regulatory materials are relevant to those important issues. Second, in an MDL with potentially thousands of individual plaintiffs, the amount in controversy is likely significant. Third, Defendants, through their foreign subsidiaries, can access the requested foreign regulatory materials. (*See* Doc. 87-2, ¶ 4 (acknowledging that foreign regulatory submissions "are located either with a subsidiary of C. R. Bard, Inc. or an International Business Center.")). Fourth, Defendants have significant resources to collect and produce the relatively narrow category of documents the Court will order to be produced.

Nonetheless, Defendants rely on *In re Bard IVC Filters Product Liability Litigation*, 317 F.R.D. 562 (D. Ariz. 2016) ("*Bard IVC Filters*") to argue that Plaintiffs' request is not proportional to the needs of this case. That case "involve[d] thousands of personal injury cases related to inferior vena cava ('IVC') filters manufactured and marketed by Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc." 289 F. Supp. 3d 1045, 1046 (D. Ariz. 2018). The "[p]laintiffs allege[d] that Bard filters are more dangerous than other IVC filters because they have a higher risk of tilting, perforating the IVC, or fracturing and migrating to neighboring organs. [They] further allege[d] that Bard failed to warn physicians and patients about these higher risks." *Id.* at 1046.

Relevant here, the plaintiffs requested "discovery of communications between the foreign entities and foreign regulatory bodies regarding the IVC filters at issue." *Bard IVC Filters*, 317 F.R.D. at 563. In response to the plaintiffs' motion, the defendants submitted an affidavit from a Bard employee, explaining that regulatory matters were handled by the defendants' employees in the United States. *Id.* at 565. Denying the plaintiffs' request, the district court concluded that the discovery sought by the plaintiffs was of limited relevance and not proportional to the needs of the case:

> ***4** Plaintiffs are engaging in substantial discovery with respect to Defendants' communications with American regulators, including extensive ESI searches and depositions of relevant witnesses. This discovery should capture communications with foreign regulators that originate in the United States, as most appear to. The Court concludes that the burden and expense of searching ESI from 18 foreign entities over a 13-year period outweighs the benefit of the proposed discovery—a mere possibility of finding a foreign communications inconsistent with United States communication.

Id. at 566.

Defendants contend that the facts of this case require the same conclusion. But this argument ignores significant factual differences between the two cases. Most importantly, unlike the defendants in *Bard IVC Filters*, Defendants have not presented the Court with any evidence with regard to the burden of production. (*See* Doc. 87 at 14–16). Instead, they merely assert that the requested discovery "would be burdensome and costly" because:

> Bard would have to identify the applicable files, which are not merely in a database, but instead located in each individual country, and search and identify all foreign regulatory

> correspondence from those files during any timeframe. In addition, Bard would then have to review the documents for relevance and privilege. Finally, Bard would have to ensure that the production complies with the various data and privacy laws of the countries in which the foreign entities are located, redact the documents pursuant to applicable law, and then produce the redacted documents.

(*Id.* at 15–16). Defendants could have provided the Court with affidavits from their employees and counsel detailing the cost in terms of time and money that such a document collection and review would require. But they have not done so, and the Court declines to rely on their conclusory assertions here. *See Ball*, 2018 WL 6242230, at *3 (holding that the burden is on the non-movant to prove that production of requested discovery would be unduly burdensome).

Further, the scope of the discovery that the Court is ordering in this case is significantly narrower than the discovery requested in *Bard IVC Filters*. The *Bard IVC Filters* plaintiffs requested "discovery of *all* communications" that 18 Bard subsidiaries "have had with foreign regulatory authorities involving *all* Bard IVC filters since 2003." 317 F.R.D. at 566 (emphasis added). In contrast, here, the Court has narrowed Plaintiffs' request to official communications between Defendants and six regulatory authorities regarding the safety and labeling of only the polypropylene hernia mesh products identified in paragraph 15 of the Master Long Form Complaint. This narrowed request will not require an exhaustive search of Defendants' and their subsidiaries' ESI. Nor will it require Defendants to search for information about all of Defendants' polypropylene surgical mesh products. Further, to alleviate any concern regarding the time-period applicable to Plaintiffs' discovery request, the Court will order the parties to meet and confer regarding this issue.

C. Premature

Finally, Defendants argue that Plaintiffs' request is premature. (Doc. 87 at 4–6). According to them, they have "agreed to produce foreign regulatory information that is contained within the United States regulatory files and non-privileged documents that hit on relevant search terms from United States custodians according to the ESI protocol, regardless of whether such documents discuss foreign regulatory matters." (*Id.* at 4), Plaintiffs, however, have not reviewed that material yet. (*Id.*). Therefore, Defendants assert, there is no need to compel the production of documents that Plaintiffs may soon receive. (*Id.* at 4–5).

***5** As an initial matter, the Court notes that this argument is in tension with Defendants' relevancy argument. On the one hand, Defendants argue that foreign regulatory materials are not relevant to this case, (*Id.* at 7–14). On the other hand, they have agreed to produce foreign regulatory materials and communications related to the same so long as they are contained in United States regulatory files or in the ESI of United States custodians. (*Id.* at 4-6).

More importantly, the Court has concluded that Plaintiffs' request, as narrowed by the Court, is relevant and proportional to the needs of the case. The Court declines to delay discovery related to this request on the off chance that some of the requested materials may be produced at some indeterminate point in the future.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Compel (Doc. 78) is **GRANTED in part and DENIED in part**. Defendants are **ORDERED** to produce official communications between Defendants and the six regulatory authorities identified in Plaintiffs' Motion (*id.* at 3–4) regarding the safety and labeling of polypropylene hernia mesh products identified in paragraph 15 of the Master Long Form Complaint. The parties are **ORDERED** to meet and confer regarding a reasonable time-period applicable to that discovery request.

IT IS SO ORDERED.

All Citations

Slip Copy, 2019 WL 341909